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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/615,305	07/13/2000	Wolfgang Meier	BioCure 101	4801

7590
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09/24/2002

EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 09/24/2002 11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/615,305

Applicant(s)

Meier

Examiner

Gollamudi Kishore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 4, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-6, 9-14, 16-20, and 27-30 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-6, 9-14, 16-20, and 27-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

The amendment filed on 4-4-2002 is acknowledged.

Claims included in the prosecution are 1, 3-6, 9-14, 16-20 and 27-30.

Claim Rejections - 35 USC § 112

- 1. The following is a quotation of the second paragraph of 35 U.S.C. 112:**

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 2. Claims 17 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

It is unclear what applicant intends to convey by 'a molecule'. What molecule? How can one incorporate just one molecule? Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that the term, molecule is defined in the Academic Press Dictionary of Science and Technology. This argument is not found to be persuasive since the issue here is not the definition of the molecule itself. The issue here is the meaning of the use of the term in singular. Since any compound or active agent is made of number of molecules and it is impossible to isolate and incorporate one single molecule, the correct expression should have been 'molecules of active agents'. The specification pages 19-22 pointed out by applicants define the incorporation of molecules of active agents and not a single molecule itself.

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Claim Rejections - 35 USC § 102

- 3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 4. Claims 1, 3-6, 9-14, 16-20 and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/49387 of record.**

WO discloses nanoparticles containing vesicles. The vesicles are made of amphiphilic triblock copolymers. Either the core domain or the shell domain is hydrophilic. The polymerization is achieved photochemically. The nanoparticles further containing a pharmaceutically active agent (note the abstract, pages 4-5, 64, 72, 87, and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that WO discloses particles made from micelles which are solid in structure and without hollow interior. This argument is not found to be persuasive since WO on page 13, line 25 clearly teaches vesicles and nowhere in the reference, the examiner finds that the core is solid. Even assuming that the core is not hollow, instant claims do not recite that the vesicles be hollow. The reference still meets the requirements of instant claims.

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5. **Claims 1, 3-6, 9-11, 16-20 and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 552 802 of record.**

EP discloses micelles made from a ABA type copolymer (note the abstract, col. 3, line 38, Examples and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments are similar to those raised for the WO reference and hence the same reasoning is applicable.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

6. **Claims 1-2, 10, 12, 17 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Pluyter (6,008,184).**

Pluyter discloses vesicles containing triblock polymers A-B-A wherein A is water soluble polymer and B is water insoluble polymer (note col 2, line 25 et seq., col. 5, lines 51-55, col. 14, lines 61-62).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Pluyter does not disclose vesicles having membranes from amphiphilic copolymers and rather the vesicles taught by Pluyter are lamellar droplets having amphiphilic copolymers attached thereto. This argument is not found to be persuasive since on col. 5, lines 53-55 Pluyter clearly teaches that the polymers are incorporated and not attached in the vesicles. This implies that the membrane of the

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vesicles are made of the polymers and instant 'comprising' does not exclude other vesicle material in Pluyter.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 1-2, 10, 12, 17 and 19 are rejected under 35 U.S.C. 102(a) as being anticipated by Martin (5,891,468).

Martin discloses liposomes (nanocapsules) made from triblock polymers. The liposomes carry targeting ligand such as folic acid (note the abstract, figures, columns 7-11, examples and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Martin does not disclose vesicles having membranes formed from amphiphilic copolymers as required by the claims and that the vesicles taught by Martin are liposomes having diblock copolymer attached to thereto. This argument is not found to be persuasive for the following reasons. First of all, instant claim language does not exclude liposomes and other material contributing to the membrane as in Martin.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention

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was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. **Claims 1, 3-6, 9-14, 16-20 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/49387 by itself or in combination with Martin cited above.**

WO, although teaches both di and tri block polymers, does not provide specific examples of the preparation of the nanoparticles using the triblock polymers. However, it is deemed obvious to one of ordinary skill in the art to prepare the nanoparticles from triblock polymer since WO provides guidance for such a preparation. One of ordinary skill in the art would be motivated further to use triblock polymers in the preparation of the nanoparticles from the guidance also provided by Martin. The use of targeting ligand in WO is deemed obvious to one of ordinary skill in the art since these ligands would target the composition to the desired sites in the body. One of ordinary skill in the art would be motivated further to include a targeting ligand such as folic acid in WO since Martin shows its routine use in vesicle preparations containing triblock polymers.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Martin does not teach stabilizing vesicles to form nanocapsules and that WO 97 does not teach hollow vesicles. Arguments based on the hollow nature of the vesicles have been addressed above. With regard to the lack of teachings of stabilization of vesicles to form nanocapsules in Martin, the examiner points out that the rationale for making the nanocapsules is provided by WO.

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10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

September 23, 2002